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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,382	08/26/2003	Imran Ahmed	033388-566	2045
21839	7590	07/15/2004	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			KISHORE, GOLLAMUDI S	
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1615

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/647,382

Applicant(s)

AHMED ET AL.

Examiner

Gollamudi S Kishore, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8-26-03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims included in the prosecution are 1-22.

Claim Rejections - 35 U.S.C. § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Instant claim 19 is drawn to method of treating cancers and applicant lists all the known forms of cancers; yet the claim is just drawn to liposomal composition without any anti-cancer agent in it. It is well within the skill of the art to recognize that cancers are not treatable with just empty liposomes or liposomes containing just biologically active agent or an antimicrobial agent as recited in claims 20-21. It is well known in the art, cancer is not a single disease and the causes are numerous. It is also well known in the art that there is no single drug or a combination of drugs, which is able to treat

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successfully all neoplastic diseases which term, "cancer" encompasses. Instant specification does not provide any data at all to show that instant composition is able to treat at least one form of cancer, let alone all varieties of cancers. One of ordinary skill in the art will not be able to select the suitable ether lipid and determine its effectiveness against cancers without undue experimentation. Furthermore, it should be pointed out that it is unclear from the specification, as recited, as to which of the compounds claimed are art known and which are not. If some or all of the compounds were novel, then it would appear that the specification does not provide adequate methodology for the preparation of the compounds.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Lung cancers, brain cancers and others recited are cancers of specific tissues and carcinomas, sarcomas etc. are specific variety of cancers, which afflict the tissues such as lung, brain and ovaries. For example, cancer of ovaries could be ovarian carcinoma. The members recited thus, are improper Markush members (claim 22).

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Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,667,053. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 recites a liposome containing an optically active ether lipid component and encompasses the liposomes in patented claims which contain the same ether lipids and other bilayer components PC, sterol and PE linked to a dicarboxylic acid. The same is the case with instant method of treatment claims and the patented claims.

7. Claims 1-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,180,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 recites a liposome containing an optically active ether lipid component and encompasses the liposomes in patented

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claims which contain a specific ether lipid and other bilayer components PC, sterol and PE linked to a dicarboxylic acid. Instant method of treatment of cancer includes various cancers recited in the patented claims.

8. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,965,159. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 recites a liposome containing an optically active ether lipid component and encompasses the liposomes in patented claims which contain a specific ether lipid and other bilayer components PC, sterol and PE linked to a dicarboxylic acid.

9. Claims 1-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,762,958. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 recites a liposome containing an optically active ether lipid component and encompasses the liposomes in patented claims which contain a specific ether lipid and other bilayer components PC, sterol and PE linked to a dicarboxylic acid. Similar is the case with instant method claims and the patented method claims.

10. Claims 19-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,017,557. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant method claim 19 recites a liposome containing

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an optically active ether lipid component and encompasses the liposomes in patented method claims which contain a specific ether lipid and other bilayer components PC, sterol and PE linked to a dicarboxylic acid. Instant specific cancers are deemed to be included in generic 'cancer' in patented claim 1.

11. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5,932,242. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 recites a liposome containing an optically active ether lipid component and encompasses the liposomes in patented claims which contain a specific ether lipid and other bilayer components PC, sterol and PE linked to a dicarboxylic acid.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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13. Claims 1, 4, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/08202 of record.

WO discloses liposomes containing ether lipids (note the abstract, page 25 and the claims). Although WO does not specifically teach whether the ether lipid is in specific optical isomer form, since instant claim recites even mixture, in the absence of showing otherwise, it is deemed that the reference meets the requirements of instant claims.

14. Claims 1, 3, 13, 14 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by TAKE (JP 61 22-020 A).

TAKE discloses liposomes containing claimed anti-tumor ether lipid (note abstract). Although TAKE does not specifically teach whether the ether lipid is in specific optical isomer form, since instant claim recites even mixture, in the absence of showing otherwise, it is deemed that the reference meets the requirements of instant claims.

15. Claims 1, 3, 13, 14 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Mende et al (Pharmazie, 1989) of record.

Mende et al disclose liposomes containing ether lipid, ET-18-OCH₃ (note abstract). Although Mende et al do not specifically teach whether the ether lipid is in specific optical isomer form, since instant claim recites even mixture, in the absence of showing otherwise, it is deemed that the reference meets the requirements of instant claims.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1, 3-4, 13-14 and 17-22 are rejected under 35 U.S.C. § 103 as being unpatentable over TAKE cited above.

As pointed out above, TAKE discloses liposomes containing claimed anti-tumor ether lipid (note abstract). TAKE does not specifically teach whether the ether lipid is in a specific optical isomer form. However, since TAKE teaches that the ether lipid is an anti-tumor ether lipid, in the absence showing otherwise, it is deemed obvious to one of ordinary skill in the art that both D and L forms of the compound or a mixture would possess the anti-tumor property. TAKE does not appear to teach the amount of the composition to be administered for cancer treatment. However, it is deemed that the amounts are manipulatable parameters since they depend upon a variety of factors including the nature of cancer, the age of the patient and the severity of the disease. TAKE does not teach the inclusion of an additional active agent or additional chemotherapeutic agent. Since combination therapy is commonly practiced in cancer treatment, it is deemed obvious to one of ordinary skill in the art to include an additional agent with the expectation of obtaining at least an additive effect.

17. Claims 1-22 are rejected under 35 U.S.C. § 103 as being unpatentable over TAKE cited above, in combination with Schroit (4,983,397) of record.

The teachings of the TAKE have been discussed above. What is lacking in TAKE is the inclusion in the liposomes of a lipid derivatized with a dicarboxylic acid.

Schroit teaches that when amine lipids, which are derivatized with dicarboxylic acids, are used in combination with other phospholipids in a liposomal form, then the uptake of those liposomes (also containing drugs) by endocytosis by macrophages is surprisingly increased (note the abstract; columns 1-2 and claims).

The inclusion of a lipid derivatized with a dicarboxylic acid in the liposomes formed from ether lipids would have been obvious to one of ordinary skill in the art because of Schroit's teachings of increased uptake of the liposomes. TAKE in addition to the ether lipids teaches the inclusion of several phospholipids, which form the liposomal bilayer. These include phosphatidylcholine (PC) and phosphatidylethanolamine (PE) with stearic acid or palmitic acids as the fatty acid moieties. Although TAKE does not specifically teach instant fatty acids in phosphatidylethanolamine, since these are art known phospholipids in liposome formation, it is deemed obvious to one of ordinary skill in the art to select PE and PC with desired fatty acids with a reasonable expectation of success.

18. Claims 17 and 20-22 are rejected under 35 U.S.C. § 103 as being unpatentable over TAKE, in combination with Schroit (4,983,397) as set forth above, in further combination with Bissery (5,908,835).

The teachings of TAKE have been discussed above. What is lacking in TAKE is the teaching of the inclusion of additional anti-cancer agent.

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Bissery teaches that compositions can be formulated to include two or more chemotherapeutic drugs to practice combination therapy and to obtain greater than the expected additive effect (abstract, col. 1, lines 28-53 and claims).

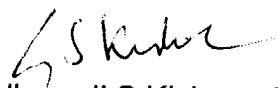
To include additional chemotherapeutic drugs in the teachings of TAKE and Schroit would have been obvious to one of ordinary skill in the art since Bissery teaches that Bissery teaches that compositions can be formulated to include two or more chemotherapeutic drugs to practice combination therapy and to obtain greater than the expected additive effect.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK